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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/737,476	12/18/2000	Leo G.J. Frenken	P 0275850 T 7060C	9341

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EXAMINER
COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
1638	18

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/737,476	FRENKEN ET AL.	
	Examiner	Art Unit	
	Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 March 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *8 and 10-13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The Amendment filed March 10, 2003, paper no. 17, has been entered.

Claims 1-6 and 9 are newly amended.

Claim 14 is newly added.

Claims 1-14 are pending.

Claims 8 and 10-13 are withdrawn from consideration.

Claims 1-7, 9 and 14 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Claim Rejections - 35 USC § 112

Claim 1 remains rejected, and claims 2, 3, 4, 5, 6 and 9 are rejected, under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "functionally equivalent". for the reasons of record set forth in the office action mailed September 10, 2002.

Applicant's arguments filed March 10, 2003, have been fully considered but they are not persuasive.

Applicants argue that the rejection should be withdrawn because the term "functionally equivalent" is defined in the specification at page 8, and Applicants further note that claim 1 has been amended to replace the term "thereto" with the appropriate antecedent (reply pages 6-7).

The Office maintains that the definition in the specification does not serve to limit the phrase "functionally equivalent" in the claims. It is still unclear what type of functional equivalence is intended, as antibodies are multifunctional proteins.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation of "devoid of a variable light chain domain". It is unclear whether the recitation of "devoid" applies to "an active fragment of said immunoglobulin" following the "devoid" clause. It is also unclear how an antibody devoid of light chain domains would also be capable of specific binding with an antigen, since antibodies are generally understood to require both light chain and heavy chain variable regions to form an antigen-specific binding site.

Claim Rejections - 35 USC § 102

Claims 1, 3, 4, 7 and 9 remain rejected, and claim 14 is rejected, under 35 U.S.C. 102(b) as being anticipated by Owen et al. (Biotechnology, Vol. 10, pages 790-794, July 1992), for the reasons of record set forth in the office action mailed September 10, 2002.

Claims 1, 3 and 6-7 remain rejected, and claim 14 is rejected, under 35 U.S.C. 102(b) as being anticipated by Artsaenko et al. (The Plant Journal, Vol. 8, No. 5, pages 745-750, 1995), for the reasons of record set forth in the office action mailed September 10, 2002.

Claims 1, 3, 4, 5 and 7 remain rejected, and claim 14 is rejected, under 35 U.S.C. 102(b) as being anticipated by Le Gall et al. (Applied and Environmental Microbiology, Vol. 64, No. 11, pages 4566-4572, November 1998), for the reasons of record set forth in the office action mailed September 10, 2002.

Claims 1 and 2 remain rejected, and claim 14 is rejected, under 35 U.S.C. 102(b) as being anticipated by Casterman et al. (WO 94/04678, 3 March 1994, Applicant's IDS), for the reasons of record set forth in the office action mailed September 10, 2002.

Applicant's arguments filed March 10, 2003, have been fully considered but they are not persuasive.

Applicants argue that since claim 1 has been amended to indicate that the recited DNA sequence encodes a heavy chain immunoglobulin that is devoid of a variable light chain domain, and since scFv molecules comprise both a heavy chain and a light chain, neither Owen et al. nor Le Gall et al. nor Artsaenko et al. anticipate the claimed invention (reply page 10).

The Office maintains that the claims as amended are not limited to DNA sequences encoding a heavy chain immunoglobulin that is devoid of a variable light chain domain. The claims are also directed to the use of a sequence encoding a protein functionally equivalent to the heavy chain immunoglobulin that is devoid of a variable light chain domain. Since a sequence encoding an scFv antibody is functionally equivalent to the heavy chain immunoglobulin that is devoid of a variable light chain domain, each of Owen et al., Le Gall et al. and Artsaenko et al. anticipate the claimed invention.

Applicants also argue that neither Owen et al. nor Le Gall et al. nor Artsaenko et al. render the claimed invention obvious because the expression of scFv antibodies in plants is subject to several drawbacks, namely low accumulation in the cytoplasm, affects on the structure and function of the organelle in which they are expressed, and the existing need for cytoplasmic targeting. Applicants argue that the claimed immunoglobulins are not subject to these drawbacks, and that none of the cited documents makes reference to them (reply pages 10-11).

Applicants' arguments are not commensurate in scope with the claims. The claims do not impose requirements with respect to accumulation in the cytoplasm, affects on the structure and function of the organelle in which they are expressed, or cytoplasmic targeting. In the absence of claim limitations directed to specific drawbacks, Applicants arguments are not relevant to the instant rejection.

Applicants further argue that the Casterman reference is not enabled by reference to Hiatt et al. Applicants also argue that there is no reason to combine Caterman et al. and Hiatt et al. because there was no reasonable expectation of success in view of the difficulties demonstrated in the prior art. Applicants point to the cited reference of Ma et al. and the Vu PhD thesis which teach the difficulty of expressing heavy chain immunoglobulins in plants (reply page 12).

The Office maintains that the Casterman reference is enabled, because it had been established that one skilled in the art could express antibodies in plants at the time of Applicants invention. That expressing heavy chain immunoglobulins in plants may be difficult is not relevant to the instant rejection in the absence of claim limitations directed to specific difficulties and excluding the prior art. Furthermore, as stated in the previous Office action at pages 11-12,

the referral to Hiatt et al. was not made to demonstrate Casterman's enablement, but to demonstrate that Casterman addressed claim limitations directed to specific promoters and signal peptides.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CC
June 1, 2003

Phuong Bui
6/2/03

PHUONG T. BUI
PRIMARY EXAMINER